\* \* \* \* \*

#### UNITED STATES (US) FOOTNOTES

\* \* \* \*

US345 In the band 401–406 MHz, the mobile, except mobile aeronautical, service is allocated on a secondary basis and is limited to, with the exception of military tactical mobile stations, Medical Device Radiocommunication Service (MedRadio) operations. MedRadio stations are authorized by rule on the condition that harmful interference is not caused to stations in the meteorological aids, meteorological-satellite, and earth exploration-satellite services, and that MedRadio stations accept interference from stations in the meteorological aids, meteorological-satellite, and earth exploration-satellite services.

\* \* \* \*

5. Section 2.1093 is amended by revising paragraph (c) to read as follows:

### § 2.1093 Radiofrequency radiation exposure evaluation: portable devices.

\* \* \* \* \*

- (a) \* \* \*
- (b) \* \* \*
- (c) Portable devices that operate in the Cellular Radiotelephone Service, the Personal Communications Service (PCS), the Satellite Communications Services, the General Wireless Communications Service, the Wireless Communications Service, the Maritime Services, the Specialized Mobile Radio Service, the 4.9 GHz Band Service, the Wireless Medical Telemetry Service (WMTS) and the Medical Device Radiocommunication Service (MedRadio), authorized under subpart H of part 22 of this chapter, parts 24, 25, 26, 27, 80 and 90 of this chapter, subparts H and I of part 95 of this chapter, and unlicensed personal communication service, unlicensed NII devices and millimeter wave devices authorized under subparts D and E, §§15.253, 15.255 and 15.257 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use. All other portable transmitting devices are categorically excluded from routine environmental evaluation for RF exposure prior to equipment authorization or use, except as specified in §§1.1307(c) and 1.1307(d) of this chapter. Applications for equipment authorization of portable transmitting devices subject to routine environmental evaluation must contain a statement confirming compliance with the limits specified in paragraph (d) of this section as part of their application. Technical information showing the basis for this statement must be submitted to the Commission upon request.

\* \* \* \* \*

6. Section 2.1204 is amended by revising paragraph (a)(9) to read as follows:

#### § 2.1204 Import conditions.

\* \* \* \* \*

- (a) \* \* \*
- (9) The radio frequency device is a medical implant transmitter inserted in a person or a medical bodyworn transmitter as defined in Part 95, granted entry into the United States or is a control transmitter associated with such an implanted or body-worn transmitter, provided, however that the transmitters covered by this provision otherwise comply with the technical requirements applicable to transmitters authorized to operate in the Medical Device Radiocommunication Service (MedRadio) under part 95 of this chapter. Such transmitters are permitted to be imported without the issuance of a grant of equipment authorization only for the personal use of the person in whom the medical implant transmitter has been inserted or on whom the medical body-worn transmitter is applied.

\* \* \* \* \*

#### PART 95 – PERSONAL RADIO SERVICES

7. The authority citation for part 95 continues to read as follows:

AUTHORITY: Sections 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303

8. Section 95.401 is amended by revising paragraph (d) to read as follows:

# § 95.401 (CB Rule 1) What are the Citizens Band Radio Services?

\* \* \* \* \*

(d) The Medical Device Radiocommunication Service (MedRadio) — an ultra-low power radio service, for the transmission of non-voice data for the purpose of facilitating diagnostic and/or therapeutic functions involving implanted and body-worn medical devices. The rules for this service are contained in subpart I of this part.

\* \* \* \* \*

9. Section 95.601 is amended by revising the last sentence to read as follows:

# § 95.601 Basis and purpose.

- \* \* \* The Personal Radio Services are the GMRS (General Mobile Radio Service)—subpart A, the Family Radio Service (FRS)—subpart B, the R/C (Radio Control Radio Service)—subpart C, the CB (Citizens Band Radio Service)—subpart D, the Low Power Radio Service (LPRS)—subpart G, the Wireless Medical Telemetry Service (WMTS)—subpart H, the Medical Device Radiocommunication Service (MedRadio)—subpart I, the Multi-Use Radio Service (MURS)—subpart J, and Dedicated Short-Range Communications Service On-Board Units (DSRCS-OBUs)—subpart L.
  - 10. Section 95.603 is amended by revising paragraph (f) to read as follows:

#### 95.603 Certification required.

\*\*\*\*

(f) Each Medical Device Radiocommunication Service (MedRadio) transmitter (a transmitter that operates or is intended to operate in the MedRadio service) must be certificated except for such transmitters that are not marketed for use in the United States, but which otherwise comply with the MedRadio Service technical requirements and are operated in the United States by individuals who have traveled to the United States from abroad.

\* \* \* \*

11. Section 95.605 is revised to read as follows:

#### § 95.605 Certification procedures.

Any entity may request certification for its transmitter when the transmitter is used in the GMRS, FRS, R/C, CB, 218-219 MHz Service, LPRS, MURS, or MedRadio Service following the procedures in part 2 of this chapter. Dedicated Short-Range Communications Service On-Board Units (DSRCS-OBUs) must be certified in accordance with subpart L of this part and subpart J of part 2 of this chapter.

12. Section 95.628 is amended by revising the title and paragraphs (a) through (f), and by adding a new paragraph (g) to read as follows:

#### § 95.628 MedRadio transmitters.

(a) Frequency monitoring. Except as provided in (b) below, all MedRadio programmer/control transmitters operating in the 401-406 MHz band must operate under the control of a monitoring system that incorporates a mechanism for monitoring the channel or channels that the MedRadio system devices

intend to occupy. The monitoring system antenna shall be the antenna normally used by the programmer/control transmitter for a communications session. Before the monitoring system of a MedRadio programmer/control transmitter initiates a MedRadio communications session, the following access criteria must be met:

- (1) \* \* \*
- (2) Within 5 seconds prior to initiating a communications session, circuitry associated with a MedRadio programmer/control transmitter must monitor the channel or channels the system devices intend to occupy for a minimum of 10 milliseconds per channel.
- (3) Based on use of an isotropic monitoring system antenna, the monitoring threshold power level must not be more than  $10\log B(Hz) 150 (dBm/Hz) + G(dBi)_{a}$  where B is the emission bandwidth of the MedRadio communications session transmitter having the widest emission and G is the MedRadio programmer/control transmitter monitoring system antenna gain relative to an isotropic antenna. For purposes of showing compliance with the above provision, the above calculated threshold power level must be increased or decreased by an amount equal to the monitoring system antenna gain above or below the gain of an isotropic antenna, respectively.
- (4) If no signal in a MedRadio channel above the monitoring threshold power level is detected, the MedRadio programmer/control transmitter may initiate a MedRadio communications session involving transmissions to and from a medical implant or medical body-worn device on that channel. The MedRadio communications session may continue as long as any silent period between consecutive data transmission bursts does not exceed 5 seconds. If a channel meeting the criteria in paragraph (a)(3) of this section is unavailable, the channel with the lowest ambient power level may be accessed.
- (5) When a channel is selected prior to a MedRadio communications session, it is permissible to select an alternate channel for use if communications are interrupted, provided that the alternate channel selected is the next best choice using the above criteria. The alternate channel may be accessed in the event a communications session is interrupted by interference. The following criteria must be met:
  - (i) \* \* \*
  - (ii) \* \* \*
- (iii) In the event that this alternate channel provision is not used by the MedRadio system or if the criteria in (i) and (ii) above are not met, a channel must be selected using the access criteria specified in paragraphs (a)(1) through (a)(4) of this section.
  - (6) \* \* \*
  - (i) \* \* \*
- (ii) MedRadio channel—Any continuous segment of spectrum in the MedRadio band that is equal to the emission bandwidth of the device with the largest bandwidth that is to participate in a MedRadio communications session. (Note: The rules do not specify a channeling scheme for use by MedRadio systems.)
- (iii) MedRadio communications session—A collection of transmissions, that may or may not be continuous, between MedRadio system devices.
- (b) Exceptions to frequency monitoring criteria. MedRadio devices or communications sessions that meet any one of the following criteria are not required to use the access criteria set forth in paragraph (a) of this section:
  - (1) MedRadio communications sessions initiated by a medical implant event.
- (2) MedRadio devices operating in either the 401-401.85 MHz or 405-406 MHz bands, provided that the transmit power is not greater than 250 nanowatts EIRP and the duty cycle for such transmissions does not exceed 0.1%, based on the total transmission time during a one-hour interval.

- (3) MedRadio devices operating in the 401.85-402 MHz band, provided that the transmit power is not greater than 25 microwatts EIRP and the duty cycle for such transmissions does not exceed 0.1%, based on the total transmission time during a one-hour interval.
- (4) MedRadio devices operating with a total emission bandwidth not exceeding 300 kHz centered at 403.65 MHz, provided that the transmit power is not greater than 100 nanowatts EIRP and the duty cycle for such transmissions does not exceed 0.01%, based on the total transmission time during a one-hour interval.
- (c) Operating frequency. MedRadio stations authorized under this Part may operate on frequencies in the 401-406 MHz band as follows provided that the out-of-band emissions are attenuated in accordance with §95.635:
- (1) MedRadio stations associated with medical implant devices, which incorporate a frequency monitoring system as set forth in paragraph (a) of this section, may operate on any of the frequencies in the 401-406 MHz band,
- (2) MedRadio stations associated with medical implant devices, which do not incorporate a frequency monitoring system as set forth in paragraph (a) of this section, may operate on any frequency in 401-402 MHz or 405-406 MHz bands, or at 403.65 MHz in the 402-405 MHz band.
- (3) MedRadio stations associated with medical body-worn devices, regardless of whether a frequency monitoring system as set forth in paragraph (a) this section is employed, may operate on any of the frequencies in the 401-402 MHz or 405-406 MHz bands.
- (4) MedRadio stations that are used externally to evaluate the efficacy of a more permanent medical implant device, regardless of whether a frequency monitoring system as set forth in paragraph (a) of this section is employed, may operate on any of the frequencies in the 402-405 MHz band, provided that:
- (i) Such external body-worn operation is limited solely to evaluating with a patient the efficacy of a fully implanted permanent medical device that is intended to replace the temporary body-worn device;
- (ii) RF transmissions from the external device must cease following the patient evaluation period, which may not exceed 30 days, except where a health care practitioner determines that additional time is necessary due to unforeseen circumstances;
- (iii) The maximum output power of the temporary body-worn device shall not exceed 200 nW EIRP; and
- (iv) The temporary body-worn device must comply fully with all other MedRadio rules applicable to medical implant device operation in the 402-405 MHz band.
- (d) Authorized bandwidth. The authorized bandwidth of the emission from a MedRadio station operating between 402-405 MHz shall not exceed 300 kHz, and no communications session involving MedRadio stations shall use more than a total of 300 kHz of bandwidth during such a session. The authorized bandwidth of the emission from a MedRadio station operating between 401-401.85 MHz or 405-406 MHz shall not exceed 100 kHz, and no communications session involving MedRadio stations shall use more than a total of 100 kHz of bandwidth during such a session. The authorized bandwidth of the emission from a MedRadio station operating between 401.85-402 MHz shall not exceed 150 kHz, and no communications session involving MedRadio stations shall use more than a total of 150 kHz of bandwidth during such a session. Note: This provision does not preclude full duplex or half duplex communications provided that the total amount of bandwidth utilized by all of the MedRadio channels employed in such a MedRadio communications session does not exceed 300 kHz in the 402-405 MHz band, or 100 kHz in the 401-402 MHz and 405-406 MHz bands.
- (e) Frequency stability. Each transmitter in the MedRadio service must maintain a frequency stability of ±100 ppm of the operating frequency over the range:

(1)\*\*\*

- (2) 0°C to 55°C in the case of MedRadio programmer/control transmitters and MedRadio body-worn transmitters.
- (f) Shared access. The provisions of this section shall not be used to extend the range of spectrum occupied over space or time for the purpose of denying fair access to spectrum for other MedRadio systems.
  - (g) Measurement procedures.
- (1) MedRadio transmitters shall be tested for frequency stability, radiated emissions and EIRP limit compliance in accordance with paragraphs (g)(2) and (g)(3) below.
  - (2) Frequency stability testing shall be performed over the temperature range set forth in (e) above.
- (3) Radiated emissions and EIRP limit measurements limit may be determined by measuring the radiated field from the equipment under test at 3 meters and calculating the EIRP. The equivalent radiated field strength at 3 meters for 25 microwatts, 250 nanowatts, and 100 nanowatts EIRP is 18.2, 1.8, or 1.2 mV/meter, respectively, when measured on an open area test site; or 9.1, 0.9, or 0.6 mV/meter, respectively, when measured on a test site equivalent to free space such as a fully anechoic test chamber. Power measurements for transmissions by stations authorized under this section may be made either in accordance with a Commission-approved peak power technique, or the following. Peak transmit power must be measured over any interval of continuous transmission using instrumentation calibrated in terms of an rms-equivalent voltage. The measurement results shall be properly adjusted for any instrument limitations, such as detector response times, limited resolution bandwidth capability when compared to the emission bandwidth, sensitivity, etc., so as to obtain a true peak measurement for the emission in question over the full bandwidth of the channel.
- (i) For a transmitter intended to be implanted in a human body, radiated emissions and EIRP measurements for transmissions by stations authorized under this section may be made in accordance with a Commission-approved human body simulator and test technique. A formula for a suitable tissue substitute material is defined in OET Bulletin 65 Supplement C (01-01).
- (ii) For a transmitter intended to be body-worn, and for programmer/control transmitters, use standard ANSI C63.4 test setup and test method.
  - 13. Section 95.631 is amended by revising paragraph (h) to read as follows:

#### § 95.631 Emission types.

\* \* \* \* \*

(h) A MedRadio station may transmit any emission type appropriate for communications in this service. Voice communications, however, are prohibited.

\*\*\*\*

14. Section 95.633 is amended by revising paragraph (e) to read as follows:

#### § 95.633 Emission bandwidth.

\* \* \* \* \*

- (e) For transmitters in the MedRadio Service:
- (1) For stations operating in 402-405 MHz, the maximum authorized emission bandwidth is 300 kHz. For stations operating in 401-401.85 MHz or 405-406 MHz, the maximum authorized emission bandwidth is 100 kHz, and stations operating in 401.85-402 MHz, the maximum authorized emission bandwidth is 150 kHz.
- (2) Lesser emission bandwidths may be employed, provided that the unwanted emissions are attenuated as provided in § 95.635. See §§ 95.628(g) and 95.639(f) regarding maximum transmitter power and measurement procedures.

\* \* \* \* \*

15. Section 95.635 is amended by revising paragraphs (b) and (d) to read as follows:

#### § 95.635 Unwanted radiation.

\* \* \* \* \*

(b) The power of each unwanted emission shall be less than TP as specified in the applicable paragraphs listed in the following table:

Transmitter	Emission type	Applicable paragraphs (b)
* * * MedRadio	* * * As specified in paragraph (d)	* * *
	* * *	

\* \* \* \* \*

- (d) For transmitters designed to operate in the MedRadio service, emissions shall be attenuated in accordance with the following: (Subparagraphs 1 through 5 pertain to MedRadio transmitters operating in the 402-405 MHz band; subparagraphs 6 through 10 pertain to MedRadio transmitters operating in the 401-402 MHz or 405-406 MHz bands)
- (1) Emissions from a MedRadio transmitter more than 250 kHz outside of the 402-405 MHz band shall be attenuated to a level no greater than the following field strength limits:

Frequency (MHz)	Field strength (μV/m)	Measurement distance (m)		
30-88	100	3		
88-216	150	3		
216-960	200	3		
960 and above	500	3		
NOTE - At band edges, the tighter limit applies.				

(2) \* \* \*

- (3) The emissions from a MedRadio transmitter must be measured to at least the tenth harmonic of the highest fundamental frequency designed to be emitted by the transmitter.
- (4) Emissions within the 402-405 MHz band more than 150 kHz away from the center frequency of the spectrum the transmission is intended to occupy will be attenuated below the transmitter output power by at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.
- (5) Emissions 250 kHz or less that are above and below the 402-405 MHz band will be attenuated below the maximum permitted output power by at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.
- (6) Emissions from medical device transmitters operating in the 401-402 MHz or 405-406 MHz bands at more than 100 kHz outside of the MedRadio bands (401-406 MHz) and all emissions in the band 406.000-406.100 MHz shall be attenuated to a level no greater than the following field strength limits:

Frequency (MHz)	Field strength (μV/m)	Measurement distance (m)		
30-88	100	3		
88-216	150	3		
216-960	200	3		
960 and above	500	3		
NOTE - At band edges, the tighter limit applies.				

- (7) The emission limits shown in (6) above are based on measurements employing a CISPR quasipeak detector except that above 1 GHz, the limit is based on measurements employing an average detector. Measurements above 1 GHz shall be performed using a minimum resolution bandwidth of 1 MHz. See also § 95.605.
- (8) The emissions from a medical device transmitter operating in the MedRadio bands (between 401-402 MHz or 405-406 MHz) must be measured to at least the tenth harmonic of the highest fundamental frequency designed to be emitted by the transmitter.
- (9) Emissions within the MedRadio bands more than 50 kHz away from the center frequency of the spectrum the transmission is intended to occupy, shall be attenuated below the transmitter output power by at least 20 dB except as noted in (7) above. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.
- (10) Emissions 100 kHz or less below 401 MHz shall be attenuated below the maximum permitted output power by at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

\* \* \* \*

16. Section 95.639 is amended by revising paragraph (f) to read as follows:

#### § 95.639 Maximum transmitter power.

\* \* \* \*

- (f) In the MedRadio Service for transmitters that are not excepted under § 95.628(b) from the frequency monitoring requirements of § 95.628(a), the maximum radiated power in any 300 kHz bandwidth by MedRadio transmitters operating at 402-405 MHz, or in any 100 kHz bandwidth by MedRadio transmitters operating at 401-402 MHz or 405-406 MHz shall not exceed 25 microwatts EIRP. For transmitters that are excepted under § 95.628(b) from the frequency monitoring requirements of § 95.628(a), the power radiated by any station operating in 402-405 MHz shall not exceed 100 nanowatts EIRP confined to a maximum total emission bandwidth of 300 kHz centered at 403.65 MHz. For transmitters that are excepted under § 95.628(b) from the frequency monitoring requirements of § 95.628(a), the power radiated by any station operating in 401-401.85 MHz or 405-406 MHz shall not exceed 250 nanowatts EIRP in any 100 kHz bandwidth and in 401.85-402 MHz shall not exceed 25 microwatts in the 150 kHz bandwidth. See §§ 95.633(e). The antenna associated with any MedRadio transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to equipment authorization. Compliance with these EIRP limits may be determined as set forth in § 95.628(g).
  - 17. Section 95.649 is revised to read as follows:

### § 95.649 Power capability.

No CB, R/C, LPRS, FRS, MedRadio, MURS, or WMTS unit shall incorporate provisions for increasing its transmitter power to any level in excess of the limits specified in § 95.639.

18. Section 95.651 is revised to read as follows:

#### § 95.651 Crystal control required.

All transmitters used in the Personal Radio Services must be crystal controlled, except an R/C station that transmits in the 26-27 MHz frequency band, a FRS unit, a LPRS unit, a MURS unit, a MedRadio transmitter, or a WMTS unit.

19. Appendix 1 to Subpart E of Part 95—Glossary of Terms is amended by removing the definition of "Medical Implant Communications Service (MICS) transmitter", "MICS" and "MICS programmer/control transmitter"; and by revising the definitions of "EIRP", "Medical implant transmitter"; and by adding the definitions of "Medical body-worn device", "MedRadio programmer/control transmitter", "MedRadio Service" and "MedRadio transmitter" in alphabetical order to read as follows:

#### APPENDIX 1 TO SUBPART E OF PART 95—GLOSSARY OF TERMS

\*\*\*\*

EIRP. Effective Isotropic Radiated Power. Antenna input power times gain for free-space or in-tissue measurement configurations required by MedRadio, expressed in watts, where the gain is referenced to an isotropic radiator.

\* \* \* \* \*

Medical body-worn device. Apparatus that is placed on or in close proximity to the human body (e.g., within a few centimeters) for the purpose of performing diagnostic or therapeutic functions.

Medical body-worn transmitter. A MedRadio transmitter intended to be placed on or in close proximity to the human body (e.g., within a few centimeters) used to facilitate communications with other medical communications devices for purposes of delivering medical therapy to a patient or collecting medical diagnostic information from a patient.

\* \* \* \* \*

Medical implant transmitter. A MedRadio transmitter in which both the antenna and transmitter device are designed to operate within a human body for the purpose if facilitating communications from a medical implant device.

MedRadio programmer/control transmitter. A MedRadio transmitter that operates or is designed to operate outside of a human body for the purpose of communicating with a receiver, or for triggering a transmitter, connected to a medical implant device or to a medical body-worn device used in the MedRadio Service; and which also typically includes a frequency monitoring system that initiates a MedRadio communications session.

MedRadio Service. Medical Device Radiocommunication Service.

MedRadio transmitter. A transmitter authorized to operate in the MedRadio service.

. .

\* \* \* \* \*

20. The title of Subpart I is revised to read as follows:

#### <u>Subpart I—Medical Device Radiocommunication Service (MedRadio)</u>

\* \* \* \* \*

21. Section 95.1201 is revised to read as follows:

# § 95.1201 Eligibility.

Operation in the MedRadio service is permitted by rule and without an individual license issued by the FCC. Duly authorized health care professionals are permitted to operate MedRadio transmitters. Persons may also operate MedRadio transmitters to the extent the transmitters are incorporated into implanted or body-worn medical devices that are used by the person at the direction of a duly authorized health care professional; this includes medical devices that have been implanted in that person or placed on the body of that person by or under the direction of a duly authorized health care professional. Manufacturers of medical devices that include MedRadio transmitters, and their representatives, are authorized to operate transmitters in this service for the purpose of demonstrating such equipment to duly authorized health care professionals. No entity that is a foreign government or which is acting in its capacity as a representative of a foreign government is eligible to operate a MedRadio transmitter. The term "duly authorized health care professional" means a physician or other individual authorized under state or federal law to provide health care services. Operations that comply with the requirements of this part may be conducted under manual or automatic control.

22. Section 95.1203 is revised to read as follows:

#### § 95.1203 Authorized locations.

MedRadio operation is authorized anywhere CB station operation is authorized under § 95.405.

23. Section 95.1205 is revised to read as follows:

#### § 95.1205 Station identification.

A station is not required to transmit a station identification announcement.

24. Section 95.1207 is revised to read as follows:

## § 95.1207 Station inspection.

Any non-implanted MedRadio transmitter must be made available for inspection upon request by an authorized FCC representative. Persons operating implanted or body-worn MedRadio transmitters shall cooperate reasonably with duly authorized FCC representatives in the resolution of interference.

25. Section 95.1209 is amended by revising paragraphs (a) through (e) to read as follows:

#### § 95.1209 Permissible communications.

- (a) Except for the purposes of testing and for demonstrations to health care professionals, MedRadio programmer/control transmitters may transmit only non-voice data containing operational, diagnostic and therapeutic information associated with a medical implant device or medical body-worn device that has been implanted or placed on the person by or under the direction of a duly authorized health care professional.
- (b) Except in response to a medical implant event, or except as provided in § 95.628(b)(3), in the 402-405 MHz band no medical implant transmitter shall transmit except in response to a transmission from a medical implant programmer/control transmitter or in response to a non-radio frequency actuation signal generated by a device external to the body in which the medical implant transmitter is implanted or is to be implanted.
- (c) MedRadio programmer/control transmitters may be interconnected with other telecommunications systems including the public switched telephone network.
- (d) For the purpose of facilitating MedRadio system operation during a MedRadio communications session, as defined in § 95.628, MedRadio transmitters may transmit in accordance with the provisions of § 95.628(a) for no more than 5 seconds without the communications of data.; MedRadio transmitters may transmit in accordance with the provisions of § 95.628(b)(3) for no more than 3.6 seconds in total within a

a one hour time period without the communications of data; MedRadio transmitters may transmit in accordance with the provisions of § 95.628(b)(2) for no more than 360 milliseconds in total within a one hour time period without the communications of data.

- (e) MedRadio programmer/control transmitters may not be used to relay information to a receiver that is not included with a medical implant or medical body-worn device. Wireless retransmission of information intended to be transmitted by a MedRadio programmer/control transmitter or information received from a medical implant or medical body-worn transmitter shall be performed using other radio services that operate in spectrum outside of the MedRadio band.
  - 26. Section 95.1211 is amended by revising paragraphs (a) through (c) to read as follows:

#### § 95.1211 Channel use policy.

- (a) The channels authorized for MedRadio operation by this part of the FCC Rules are available on a shared basis only and will not be assigned for the exclusive use of any entity.
- (b) To reduce interference and make the most effective use of the authorized facilities, MedRadio transmitters must share the spectrum in accordance with § 95.628.
- (c) MedRadio operation is subject to the condition that no harmful interference is caused to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services. MedRadio stations must accept any interference from stations operating in the 400.150-406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services.
  - 27. Section 95.1213 is revised to read as follows:

# § 95.1213 Antennas.

No antenna for a MedRadio transmitter shall be configured for permanent outdoor use. In addition, any MedRadio antenna used outdoors shall not be affixed to any structure for which the height to the tip of the antenna will exceed three (3) meters (9.8 feet) above ground.

28. Section 95.1215 is amended by removing the parenthetical letter "(a)" at the beginning of the text and revising the remainder of the text to read as follows:

#### § 95.1215 Disclosure polices.

Manufacturers of MedRadio transmitters must include with each transmitting device the following statement:

"This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference."

29. Section 95.1217 is amended by revising paragraphs (a) through (c) to read as follows:

# § 95.1217 Labeling requirements.

(a) MedRadio programmer/control transmitters shall be labeled as provided in part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

"This device may not interfere with stations operating in the 400.150-406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation."

The statement may be placed in the instruction manual for the transmitter where it is not feasible to place the statement on the device.

- (b) Where a MedRadio programmer/control transmitter is constructed in two or more sections connected by wire and marketed together, the statement specified in this section is required to be affixed only to the main control unit.
- (c) MedRadio transmitters shall be identified with a serial number. The FCC ID number associated with a medical implant transmitter and the information required by § 2.925 of the FCC Rules may be placed in the instruction manual for the transmitter and on the shipping container for the transmitter, in lieu of being placed directly on the transmitter.
  - 30. Section 95,1219 is revised to read as follows:

# § 95.1219 Marketing limitations.

Transmitters intended for operation in the MedRadio Service may be marketed and sold only for the permissible communications described in § 95,1209 of this part.

31. Subpart I is amended by adding a new section 95.1221 to read as follows:

#### <u> § 95.1221 RF exposure.</u>

MedRadio medical implant or medical body-worn transmitters (as defined in appendix 1 to subpart E of part 95 of this chapter) are subject to the radiofrequency radiation exposure requirements specified in §§ 1.1307 and 2.1093 of this chapter, as appropriate. Applications for equipment authorization of implant devices operating under this section must contain a finite difference time domain (FDTD) computational modeling report showing compliance with these provisions for fundamental emissions. The Commission retains the discretion to request the submission of specific absorption rate measurement data.

# APPENDIX B

# Parties Filing Comments In RM-11271

	<del>-</del>	
AdvaMed	Guidant Corporation	Quallion LLC
Advanced Bionics	Henry G. Stifel	Richard Andersen, Ph.D.
Alfred Mann Foundation	Henry Mayo Newhall Memorial Hospital	Richard B. North, MD
American Association of People with Disabilities or AAPD	Herb Schorr, Ph.D.	Robert B. Strother, Jr.
AMI Semiconductors, Inc. (now "ON Semiconductor Corp.")	HMRI	Robert R. Myers, Ph.D.
Apostolos P. Georgopoulos, MD, PhD	House Ear Institute	Roger D. Madison, Ph.D.
Argonne National Laboratory	Implanted Acoustics	Ross Davis, M.D.
Biogenic Research Corporation	International Functional Electrical Stimulation Society	Roundtrip LLC
Bioness Inc.	J. Thomas Mortimer, Ph.D.	RTI International
Biotronik, Inc.	James R. Buckett	Scot Decristofaro
Bosley	James S. Walter, PhD	Second Sight
Brenda J. Arndt	John W. McDonald, M.D., Ph.D.	Shepherd Center
Carlana Stone Lawson	Julia M. Olson	Shriners Hospitals for Children
College of the Canyons	Kenneth Rodgers	St. Jude Medical
Cyberkinetics Neutrotechnology Systems, Inc.	Kent Kresa	Stellar Microelectronics, Inc.
Dana Brown	Leidner & Leidner, A.P.C.	STMicroelectronics, Inc.
David A. Larson	Lucinda L. Baker PT, PhD	The Los Angeles Gerontology Research Group
Department of the Army	MannKind Corporation	The Media Laboratory
Department of Veteran Affairs	Margaret Giannini	Themis R. Kyriakides, Ph.D.
DexCom, Inc.	Mark A. Liker, M.D.	Timex Corporation
Doheny Eye Institute	Medtronic, Inc.	Transoma
Donald Garretson	Michael C Harris	Tulane University
Donald W. Nielsen, Ph.D.	National Institute on Disability and Rehabilitation	United Cerebral Palsy
Dr Richard Mellish, Medicines & Healthcare Products Regulatory Agency	Neural Signals Inc	University of California, Los Angeles
Dr. Arthur Prochazka	NeuroSystec Corporation	University of California, Santa Cruz
Dr. Jane Burridge	Neurotech Network	University of Pittsburgh
Dr. Joseph P. Pancrazio	Northwestern University	University of Utah
Elbert E. Hardeman	ORBCOMM Inc.	UWEB
Electronic Technology Solutions	Paralyzed Veterans of America	V. Reggie Edgerton, Ph.D.
F. Terry Hambrecht, M.D.	Partners HealthCare System	W. Dean Baker, PhD
Gad Alon Ph.D., PT	Peter Pitsch	Zarlink Semiconductor Inc.
GE Healthcare	Pritzker Institute of Biomedical Science & Engineering	
Community Community M.D.	Deefees Deese Deises	

Professor Roger Briggs

George H. Crossley III, M.D.

#### APPENDIX C

## Final Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act (RFA), an Initial Regulatory Flexibility Analysis (IFRA) was incorporated in the Notice of Proposed Rulemaking, Notice of Inquiry and Order (MedRadio Notice) in ET Docket No. 06-135. The Commission sought written public comment on the proposals in the MedRadio Notice, including comment on the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

#### A. Need for and Objectives, of the Report and Order.

The Report and Order establishes the Medical Device Radiocommunication Service (MedRadio) under Part 95 of the Commission's rules. This new service will incorporate the existing Medical Implant Communications Service (MICS) "core" band at 402-405 MHz, and include two megahertz of newly designated spectrum in the adjacent "wing" bands at 401-402 MHz and 405-406 MHz. Altogether, the MedRadio Service will provide a total of five megahertz of contiguous spectrum for advanced wireless medical radiocommunication devices to be used for diagnostic and therapeutic purposes in humans. Among other benefits, the MedRadio Service will accommodate the operation of body-worn as well as implanted medical devices, including those using either LBT or non-LBT spectrum access methods, in designated portions of the 401-406 MHz band.

Significant advances in wireless implanted and body-worn medical technologies are revolutionizing treatment for a wide variety of medical conditions and, even more fundamentally, creating new health care models serving to improve quality of life for all Americans. As demonstrated by the comment record in this proceeding, implanted and body-worn medical devices that rely upon wireless technologies are being used even today to treat a variety of cardiac and diabetic conditions. For example, wireless implanted cardiac devices serve as defibrillators and pacemakers without the need for external wired connections; while other radio-equipped devices, such as blood glucose monitors and insulin pumps, support more timely treatment for diabetic patients and allow physicians to wirelessly retrieve data and then make operating parameter adjustments with greater ease and accuracy than with the more traditional wired connection technologies. Some examples of newer generations of devices that could benefit from the use of wireless technologies include implanted vagus nerve stimulators that send electric pulses to the brain to treat severe chronic depression, and deep brain stimulators used to treat tremors related to Parkinson's disease.<sup>3</sup> Such advances have the potential to significantly improve the quality of life and sophistication of therapy for countless Americans living with a variety of medical conditions; and, in turn, could result in lower medical costs and extend the time between hospital visits and surgical procedures.

#### B. Summary of Significant Issues Raised by Public Comments in Response to the IRFA.

There were no comments filed that specifically addressed the rules and policies proposed in the IRFA.

See 5 U.S.C. § 603. The RFA, see 5 U.S.C. § 60-612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1966 (SBREFA), Public Law No. 104-121, Title II, 110 Stat. 857 (1996).

<sup>&</sup>lt;sup>2</sup> Investigation of the Spectrum Requirements for Advanced Medical Technologies, Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz, DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules, ET Docket No. 06-135, RM-11271, Notice of Proposed Rulemaking and Notice of Inquiry and Order, (MedRadio Notice) 21 FCC Rcd 8164 (2006).

<sup>&</sup>lt;sup>3</sup> *Id*.

# C. Description and Estimate of the Number of Small Entities to Which the Rules Will Apply.

The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted.<sup>4</sup> The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.<sup>6</sup> A small business concern is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.<sup>7</sup>

Nationwide, there are a total of approximately 22.4 million small businesses, according to SBA data.<sup>8</sup> A "small organization" is generally "any not-for-profit enterprise which is independently owned and operated and is not dominant in its field." Nationwide, as of 2002, there were approximately 1.6 million small organizations.<sup>10</sup> The term "small governmental jurisdiction" is defined generally as "governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand." Census Bureau data for 2002 indicate that there were 87,525 local governmental jurisdictions in the United States.<sup>12</sup> We estimate that, of this total, 84,377 entities were "small governmental jurisdictions." Thus, we estimate that most governmental jurisdictions are small.

Personal Radio Services. The Medical Device Radio Communications Service are being placed within Part 95 of our rules ("Personal Radio Services"). Personal radio services provide short-range, low power radio for personal communications, radio signaling, and business communications not provided for in other services. The Personal Radio Services include spectrum licensed under Part 95 of our rules and covers a broad range of uses. Many of the licensees in these services are individuals, and thus are not small entities. In addition, due to the fact that licensing of operation under Part 95 is accomplished by rule (rather than by issuance of individual license), and due to the shared nature of the spectrum utilized by some of these services, the Commission lacks direct information other than the census data above, upon which to base an estimation of the number of small entities under an SBA definition that might be directly affected by the proposed rules.

<sup>&</sup>lt;sup>4</sup> 5 U.S.C. § 603(b)(3).

<sup>&</sup>lt;sup>5</sup> 5 U.S.C. § 601(6).

<sup>&</sup>lt;sup>6</sup> 5 U.S.C. § 601(3) (incorporating by reference the definition of "small business concern" in 15 U.S.C. § 632). Pursuant to the RFA, the statutory definition of a small business applies "unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register." 5 U.S.C. § 601(3).

<sup>&</sup>lt;sup>7</sup> Small Business Act, 15 U.S.C. § 632 (1996).

<sup>&</sup>lt;sup>8</sup> See SBA, Programs and Services, SBA Pamphlet No. CO-0028, at page 40 (July 2002).

<sup>&</sup>lt;sup>9</sup> 5 U.S.C. § 601(4).

<sup>&</sup>lt;sup>10</sup> Independent Sector, The New Nonprofit Almanac & Desk Reference (2002).

<sup>11 5</sup> U.S.C. § 601(5).

<sup>&</sup>lt;sup>12</sup> U.S. Census Bureau, Statistical Abstract of the United States: 2006, Section 8, page 272, Table 415.

We assume that the villages, school districts, and special districts are small, and total 48,558. See U.S. Census Bureau, Statistical Abstract of the United States: 2006, section 8, page 273, Table 417. For 2002, Census Bureau data indicate that the total number of county, municipal, and township governments nationwide was 38,967, of which 35,819 were small. *Id*.

<sup>14 47</sup> CFR Part 90.

We do note, however, that the designation for the two megahertz of spectrum for the Medical Device Radio Communications Service would be limited to use by medical implant and body-worn medical devices and, thus, would not be shared with other non-Federal Governmental uses. To date, there are only a small number of manufacturers (i.e., less than ten – maybe five or so) that produce these devices, and FDA approval must be secured before such devices are brought to market. Due to the stringent FDA approval requirements, the small number of existing medical device manufacturers tends to focus very narrowly on this highly specialized market niche.

Wireless Communications Equipment Manufacturers. The Census Bureau does not have a category specific to medical device radiocommunication manufacturing. The appropriate category is that for wireless communications equipment manufacturers. The Census Bureau defines this category as follows: "This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment." The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, which is: all such firms having 750 or fewer employees. According to Census Bureau data for 2002, there were a total of 1,041 establishments in this category that operated for the entire year. Of this total, 1,010 had employment of under 500, and an additional 13 had employment of 500 to 999. Thus, under this size standard, the majority of firms can be considered small. 16

Wireless Service Providers. The SBA has developed a small business size standard for wireless firms within the two broad economic census categories of "Paging" and "Cellular and Other Wireless Telecommunications." Under both categories, the SBA deems a wireless business to be small if it has 1,500 or fewer employees. For the census category of Paging, Census Bureau data for 2002 show that there were 807 firms in this category that operated for the entire year. Of this total, 804 firms had employment of 999 or fewer employees, and three firms had employment of 1,000 employees or more. Thus, under this category and associated small business size standard, the majority of firms can be considered small. For the census category of Cellular and Other Wireless Telecommunications, Census Bureau data for 2002 show that there were 1,397 firms in this category that operated for the entire year.

<sup>15</sup> NAICS code 334220.

<sup>&</sup>lt;sup>16</sup> NAICS code 11210.

<sup>&</sup>lt;sup>17</sup> 13 C.F.R. § 121,201, NAICS code 517211.

<sup>&</sup>lt;sup>18</sup> 13 C.F.R. § 121.201, NAICS code 517212.

<sup>&</sup>lt;sup>19</sup> U.S. Census Bureau, 2002 Economic Census, Subject Series: "Information," Table 5, Employment Size of Firms for the United States: 2002, NAICS code 517211 (issued Nov. 2005).

<sup>&</sup>lt;sup>20</sup> Id. The census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is for firms with "1000 employees or more."

<sup>&</sup>lt;sup>21</sup> U.S. Census Bureau, 2002 Economic Census, Subject Series: "Information," Table 5, Employment Size of Firms for the United States: 2002, NAICS code 517212 (issued Nov. 2005).

Of this total, 1,378 firms had employment of 999 or fewer employees, and 19 firms had employment of 1,000 employees or more.<sup>22</sup> Thus, under this second category and size standard, the majority of firms can, again, be considered small.

**Public Safety Radio Services.** Public Safety radio services include police, fire, local government, forestry conservation, highway maintenance, and emergency medical services. <sup>23</sup> For small businesses in this category, the above small business size standard applies to 1500 or fewer employees. There are a total of approximately 127,540 licensees in these services. Governmental entities <sup>24</sup> as well as private businesses comprise the licensees for these services. All governmental entities with populations of less than 50,000 fall within the definition of a small entity. <sup>25</sup>

# D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities.

We are using the licensing approach for the entire 401-406 MHz MedRadio band that is identical to that used for the existing MICS band at 402-405 MHz. Thus, rather than require individual transmitter licensing, the Commission authorizes operation by rule within the Citizens Band (CB) Radio Service under Part 95 of our Rules and pursuant to Section 307(e) of the Communications Act. Licensing will be accomplished through adherence to applicable technical standards and other operating rules (unlicensed operations). We conclude that this approach is beneficial because it would minimize the administrative burden on prospective licensees as compared with an individual licensing scheme.

24 47 CFR § 1.1162.

25 5 U.S.C. § 601(5).

<sup>&</sup>lt;sup>22</sup> Id. The census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is for firms with "1000 employees or more."

<sup>23</sup> With the exception of the special emergency service, these services are governed by Subpart B of part 90 of the Commission's Rules, 47 C.F.R. §§ 90.15-90.27. The police service includes approximately 27,000 licensees that serve state, county, and municipal enforcement through telephony (voice), telegraphy (code) and teletype and facsimile (printed material). The fire radio service includes approximately 23,000 licensees comprised of private volunteer or professional fire companies as well as units under governmental control. The local government service that is presently comprised of approximately 41,000 licensees that are state, county, or municipal entities that use the radio for official purposes not covered by other public safety services. There are approximately 7,000 licensees within the forestry service which is comprised of licensees from state departments of conservation and private forest organizations who set up communications networks among fire lookout towers and ground crews. approximately 9,000 state and local governments are licensed to highway maintenance service provide emergency and routine communications to aid other public safety services to keep main roads safe for vehicular traffic. The approximately 1,000 licensees in the Emergency Medical Radio Service (EMRS) use the 39 channels allocated to this service for emergency medical service communications related to the delivery of emergency medical treatment. 47 CFR §§ 90.15-90.27. The approximately 20,000 licensees in the special emergency service include medical services, rescue organizations, veterinarians, handicapped persons, disaster relief organizations, school buses, beach patrols, establishments in isolated areas, communications standby facilities, and emergency repair of public communications facilities. 47 CFR §§ 90.33-90.55.

<sup>&</sup>lt;sup>26</sup> See Medtronic Petition at i, 16, and Appendix A, at proposed section § 95.1601. We note that 47 U.S.C. § 307(e)(3) provides that the term "citizens band radio service" shall have the meaning given it by the Commission by rule. 47 U.S.C. § 307(e)(1) provides that upon determination by the Commission that an authorization serves the public interest, convenience, and necessity, the Commission may by rule authorize the operation of radio stations without individual licenses in the citizens band radio service.

# E. Steps Taken to Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered.

The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.<sup>27</sup>

In the Report and Order we are establishing a new Medical Device Radiocommunication Service (MedRadio Service) under Part 95, which will encompass all medical devices permitted to operate in the 401-406 MHz band. We sought comment on the options concerning whether and how the five megahertz of spectrum that would comprise this MedRadio band could be divided among the evolving varieties of both implanted and body-worn medical transmitters, including low-power, low-duty-cycle (LPLDC) devices that do not employ "listen-before-talk" (LBT) frequency monitoring spectrum access techniques.

Report to Congress: The Commission will send a copy of the Report and Order, including this FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act.<sup>28</sup> In addition, the Commission will send a copy of the Report and Order, including this FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the Report and Order and FRFA (or summaries thereof) will also be published in the Federal Register.<sup>29</sup>

<sup>&</sup>lt;sup>27</sup> See 5 U.S.C. § 603(c).

<sup>&</sup>lt;sup>28</sup> See 5 U.S.C. § 801(a)(1)(A).

<sup>&</sup>lt;sup>29</sup> See 5 U.S.C. § 604(b).

# STATEMENT OF ACTING CHAIRMAN MICHAEL I. COPPS

RE: Investigation of the Spectrum Requirements for Advanced Medical Technologies, ET Docket No. 06-135; Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405-406 MHz, RM-11271; DexCom, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 05-213; Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 03-92

Few uses of our spectrum could be more important than supporting new medical technologies that can extend and improve lives. Our nation's medical researchers continue to develop extraordinary bodyworn and implanted devices that are used to treat a variety of health conditions with less invasive patient treatment options. Today's order takes us another major step forward with the establishment of a new Medical Device Radiocommunication Service, which incorporates the existing Medical Implant Communications Service band with additional spectrum for advanced wireless medical radiocommunication devices used for diagnostic and therapeutic purposes. Among other things, these devices are used to control heart rhythms to prevent attacks, mitigate the tremors of neurological patients, and control the delivery of insulin to patients with diabetes.

I am always pleased to support these kinds of achievements. Once again I thank our Office of Engineering and Technology, working in conjunction with the National Telecommunications and Information Administration (NTIA), for developing these new rules.

# STATEMENT OF COMMISSIONER JONATHAN S. ADELSTEIN

RE: Investigation of the Spectrum Requirements for Advanced Medical Technologies, ET Docket No. 06-135; Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405-406 MHz, RM-11271; DexCom, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 05-213; Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Report and Order ET Docket No. 03-92

With the approval of the new Medical Device Radiocommunication Service, the Commission is helping to facilitate exciting new medical technologies that will improve our lives. The addition of two megahertz of spectrum to the Medical Implant Communications Service band will be used for advance diagnostic, monitoring, and therapeutic wireless radiocommunication devices that can help doctors better treat their patients and benefit the health and comfort of so many. I hope that the order will spark more research and new medical applications so that we may continue to make strides in health care. For these reasons, I am pleased to support this order. I thank the National Telecommunication and Information Administration and our Office of Engineering and Technology for their work in crafting these rules.

# STATEMENT OF COMMISSIONER ROBERT M. McDOWELL

RE: Investigation of the Spectrum Requirements for Advanced Medical Technologies, ET Docket No. 06-135; Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405-406 MHz, RM-11271; DexCom, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 05-213; Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 03-92

It is with great pleasure that I vote to approve this order, which establishes a new Medical Device Radio Communications Service and provides five megahertz of contiguous spectrum to power advanced diagnostic and therapeutic wireless devices. Our action today provides direct help to millions of people suffering from a variety of medical conditions such as diabetes, Parkinson's disease, depression and cardiac ailments, to name a few.

I am excited about the notices of proposed rulemaking that will result from our decision in this proceeding. The Alfred Mann Foundation has undertaken pioneering research that harnesses wireless technology to provide medical treatment and therapy to patients suffering from paralysis. In addition, GE Medical Systems is developing advanced body sensing technologies that would allow continuous patient monitoring whether the patient is located within or outside of a hospital setting. Similarly worthwhile is the proposal submitted by ON Semiconductor, which has the potential to deliver new and innovative services to the hearing impaired community. I am pleased that we will consider moving forward to develop a record through a notice of proposed rulemaking to more fully analyze the relevant issues.

Many thanks to our team in the Office of Engineering and Technology, and our colleagues at the National Telecommunications and Information Administration, for your dedication and diligence. I look forward to learning about future scientific breakthroughs that result from your work, that of the private sector, as well as the important action taken by the Commission today.